This record is a partial extract of the original cable. The full text of the original cable is not available.

070954Z Dec 05

UNCLAS SECTION 01 OF 06 BANGKOK 007526

SIPDIS

SENSITIVE

DEPARTMENT PASS USTR FOR BWEISEL, VESPINEL
GENEVA FOR USTR
COMMERCE FOR ITA/MAC/AP/OKSA/JBENDER AND JKELLY
HHS FOR OGHA STEIGER, ELVANDER AND BHAT
USPTO FOR DKEATING AND MMOEZIE

E.O. 12958: N/A
TAGS: ECON ETRD KIPR TH
SUBJECT: PHARMACEUTICAL COSTS AND THE FTA

¶1. (U) Summary and Introduction: The prospect of strong "TRIPS-plus" patent provisions in a U.S.-Thailand Free Trade Agreement (FTA) has been a controversial issue in Thailand. Anti-FTA activists from NGOs and within the RTG claim that stronger patent protection for pharmaceutical products in an FTA with the U.S. would prevent or delay the production of cheaper generic drugs to compete with pharmaceutical imports. They fear the FTA would raise overall health costs and prevent access to cheap essential medicines desperately needed in a developing nation with scarce resources to fund large-scale health programs, particularly for HIV/AIDS treatment.

¶2. (U) The immediate effect of the FTA on pharmaceutical costs in Thailand would appear to be low. Although the patent system and market exclusivity it provides to pharmaceutical companies has kept the prices of some drugs high, there are few drugs currently on the market whose costs would be further affected by the patent provisions likely to be included in an FTA. Delays in patent and marketing approval that could add extra life to patent terms under an FTA are few and manageable with additional resources. Thailand has a capable generic pharmaceutical industry that can copy most any drug, but the likelihood is low that the RTG would break the patent on any given drug and produce it generically, despite frequent demands by FTA critics.

¶3. (U) This cable aims to examine the potential effects of an FTA on pharmaceutical costs in Thailand. Although a patent chapter has yet to be introduced by either side in FTA negotiations, previous U.S. FTAs with other nations give some indication as to what patent provisions could look like in a U.S.-Thai FTA. End Summary and Introduction.

Pharma in a nutshell

¶4. (U) According to industry analysts, the pharmaceutical industry in Thailand had revenues of over USD 1.4 billion in 2004 and has been growing an average of 12 percent over the last five years. Approximately 3000 pharmaceutical products are on the market in Thailand, both original products and generic copies. Multinational firms control approximately 60 percent of market share, though two Thai firms break the list of top ten largest firms, Siam Pharmaceuticals and the state-owned Government Pharmaceutical Organization which almost exclusively produce generic products. An estimated 25 percent of pharmaceutical imports came from U.S.-based companies in 2004, but given the global nature of most pharmaceutical companies, teasing out what percentage of imports was produced in which country is difficult to accomplish. U.S.-based pharmaceutical giant Pfizer is the industry leader in Thailand; Merck and Bristol-Myers Squibb make the top ten as well.

What's the problem?

¶5. (U) Health care activists in a number of Thai and international NGOs claim that increased patent and data protection for pharmaceutical products resulting from an FTA with the U.S. could delay the introduction of cheaper generic competitors. As drug expenditures account for approximately 30 percent of total health care expenditure in Thailand, there is great concern for availability of cheap medicines to stretch the Thai health care budget. A recent and somewhat alarmist study by the Ministry of Public Health predicted that an FTA could raise annual health care costs by as much as USD five billion. Although even NGO activists admitted that number was wildly unrealistic, Thai FTA negotiators have cited the figure as a reason for concern in negotiations with the U.S. on IPR.

¶6. (U) Despite the range of products on the market in Thailand (and the range of maladies), concern with the FTA

and pharmaceuticals has focused almost exclusively on HIV/AIDS medicines and the impact of an FTA on treatment for the large number of patients in Thailand. Despite a successful campaign in the 1990s to slow the spread of AIDS, approximately 570,000 Thais are HIV positive. The World Bank estimated that nearly 50,000 Thais died from AIDS in 2004, though the death rate has been decreasing as treatment improves and becomes more widespread. The Bank estimated nearly 20,000 new cases of HIV occurred in 2004.

¶7. (U) The RTG Ministry of Public Health (MoPH) has allocated 2.7 billion Baht (USD 66 million) for implementation of an anti-retroviral treatment scheme for FY2006. MOPH has set a goal to provide free treatment to 80,000 HIV positive patients under the universal health care scheme. Health officials say that although there are 570,000 HIV positive cases in Thailand, only 100-120,000 have reached the stage of the disease where treatment is necessary, making the MoPH goal close to near universal treatment for patients who require it.

¶8. (U) Thailand's Government Pharmaceutical Organization (GPO) makes its own generic antiretroviral cocktail, GPO-vir, a cocktail of three anti-retrovirals (ARVs) which are off patent. Approximately 70,000 of the patients to be treated under MoPH's program will receive GPO-vir at a cost to the RTG of only a dollar a day per patient. However, drug resistance to GPO-vir has increased over the past two years and an additional 10,000 patients in the MoPH program require second-line ARVs to continue treatment. The few second-line ARV cocktails available include drugs patented in Thailand by multinational pharmaceutical companies, and are available only at up to ten times the cost of first-line regimens. As more AIDS patients build resistance to the first-line ARVs, the number of patients needing more expensive second-line treatment will only increase.

Patent term restoration, or unnecessary extension?

¶9. (U) FTA critics point to provisions in recent U.S. FTAs that affect pharmaceutical products and could restrict access to essential medicines in Thailand. Recent U.S. FTAs include articles that require governments to lengthen the term of a patent to compensate the patent holder for any unreasonable delays in the issuance of the patent or during the marketing approval process. The pharmaceutical industry considers this just compensation for opportunity lost to sell their product with market exclusivity. FTA critics call it an unwarranted extension of the 20-year patent term, and fear that it will delay the introduction of cheaper generic competitors.

¶10. (U) FTA patent provisions would unlikely have an immediate effect on drug patent terms. At present, few pharmaceuticals are under patent in Thailand as the RTG only recently began accepting pharmaceutical patent applications in September, 1992. Owing to the sometimes decade-long process of creation of a new drug, many if not most of the chemical compounds which have been submitted for patent approval in Thailand have yet to reach market.

¶11. (SBU) A U.S.-Thai FTA would also not appear to have any immediate effect on availability or price of ARVs in Thailand. At present, only four of the 13 ARVs on Thailand's National List of Essential Drugs (NLED) are under patent. GPO already makes generic copies of most unpatented ARVs on the NLED and would presumably continue to do so post-FTA. There are other ARVs not on the NLED that are patented as well, but industry analysts knew of none (on or off the NLED) that would receive patent term extension from an FTA.

¶12. (SBU) Despite patent protection and the market exclusivity that it allows, pharmaceutical companies in Thailand claim they do not charge excessive monopoly prices on their products. Most companies practice price differentiation, selling their products at a steep discount from what they would charge in the U.S. in recognition of the different level of income in Thailand. In addition, despite the patent, companies still face competition from other products which, while not precisely the same, have similar purposes. Thailand is a respectably-sized market and there is ample presence of most major multinational pharmaceutical companies, not to mention a domestic generic industry that competes strongly in off-patent products. Nevertheless, one company estimated the price dropped an average of 40 percent after the end of a drug's patent protection.

Unreasonable delays in patent and market approval?

¶13. (U) The pharmaceutical industry complains of excessive delays in awarding patents and cites an average of five years to approve a patent on a pharmaceutical product. Mr. Suradet Atsawintarangkun, head of the biotechnology section of the Thai Patent Office (TPO), insisted that his section processed most applications for new chemical compounds within one or

two years, five years at the outside. Econoff toured the TPO where five patent examiners specialized in pharmaceutical and biotech products. Desks were piled high with some of the estimated 100 new applications received monthly, most inches thick with detailed scientific data on the new chemical compounds.

¶14. (U) One point on which nearly everyone agrees is that the TPO is strained for resources. TPO's Suradet said patent applications were increasingly complicated and hi-tech and examiners were pressed to thoroughly check data in patent applications. Most examiners in the biotech section were graduates of Masters-level science programs, but Suradet admitted that the TPO found it difficult to compete with the private sector for the best graduates. Examiners tended to rely heavily on patent approval reports by the U.S. Patent & Trademark Office, but nevertheless made their own determinations. Applications from foreign firms were difficult as well because technical experts from the firms were not nearby to answer technical questions. The lengthy process of sending examiners' questions from TPO through a series of lawyers to the patent applicant and finally back again added further delays.

¶15. (U) Delays in issuance of patents are not a primary concern of the pharmaceutical industry in Thailand as the patent is typically examined and approved while companies are still engaged in the lengthy research and development of a new drug. However, drug companies are concerned with uncertainty in the process and great variation in the length of time required for a patent to be approved. Although some drugs take many years to produce, others are ready for market relatively quickly.

¶16. (U) The industry is more concerned for potential delays in the market approval process, as at this stage a new drug is ready for marketing and delays mean lost revenue. However, in contrast to their grumblings about the TPO, the pharmaceutical industry had few complaints about market approval. The Thai Food and Drug Administration (TFDA) has responsibility for determining the quality, safety and efficacy of new drugs before allowing them on the market. The TFDA gives itself 180 working days to approve a new drug, though the clock stops if additional information is required from the submitting company. Most approvals are issued in an acceptable 12-18 month range, though the TFDA can process an application much more quickly for life-saving drugs it would like to speed to market.

Data exclusivity) protecting secret data or blocking out generics?

¶17. (U) Data exclusivity provisions in a proposed FTA have also been controversial. Typical provisions in an FTA require governments to protect clinical test data submitted in support of marketing approval for five years after product approval, not only from disclosure to other parties, but also to essentially prevent generic manufacturers from relying on test data submitted by other companies to support applications for market approval for their own generic copies, regardless of whether the product was ever patented.

¶18. (U) Current Thai law under the Trade Secrets Act provides for protection for clinical test data, though implementing regulations have yet to be approved. TFDA keeps test data under lock and key and there have been no complaints of leaks of confidential data. However, there are no restrictions on generic firms from relying on test data from the original producers when submitting generic copies for approval. Although the generic firms never see the data, the TFDA will accept an application for market approval for a generic drug shown to be bioequivalent to the original drug and accept that the drug has already been proven to be safe and effective based on earlier approval with the original test data.

¶19. (U) Protection of clinical test data is a high priority for the pharmaceutical industry as a majority of their products were never patented in Thailand, either because of the unavailability of patents before 1992 or simply because the market was not considered important enough to warrant the cost of the patent filing. Pharmaceutical companies claim that the costs of product development and clinical testing of new drugs can run into the hundreds of millions and call for data exclusivity to protect that investment. Generic drug firms in Thailand currently have a significant competitive advantage in foregoing expensive and lengthy testing of their own to produce a generic copy, but these firms and the RTG question the logic of forcing generic producers to needlessly undertake the same clinical tests that the original producer had already completed years before. They claim the end result would be delays in the introduction of cheaper generics, even for products that were never patented.

¶20. (U) The Thai pharmaceutical industry association, Prema,

believes only a handful of drugs (none of them ARVs) would receive immediate benefit from an FTA regarding data exclusivity. As data exclusivity is typically granted for only five years, an FTA would affect only those drugs that came on the market in the previous five years. Approximately 30 new innovative drugs come on the Thai market every year, meaning an estimated 150 drugs could benefit from data exclusivity at any given time after an FTA entered into force. However, the increasing prevalence of patent filings in Thailand means most drugs of any commercial importance will acquire patent protection (and therefore already have market exclusivity) and data exclusivity will increasingly become less crucial.

Compulsory licensing

¶21. (U) FTA critics also point to restrictions in previous FTAs on the terms under which a country may issue a compulsory license. Under certain conditions WTO rules allow local manufacturers to produce a patented medicine without license from the original manufacturer. These conditions include the existence of a public health emergency for which the medicine is required.

¶22. (U) Despite frequent urgings by NGO activists and MoPH, the RTG has yet to issue a compulsory license for any drug. Activists readily attribute this to USG pressure and RTG unwillingness to damage the bilateral relationship with the U.S. However, an industry analyst suggested that GPO realized it simply would not be cost-effective to produce some generics under a compulsory license, no matter the need. The costs involved in producing a generic copy, including the cost of importing ingredients, research and development, and license fees to the patent holder could surpass the cost of simply purchasing the product.

¶23. (SBU) NGO activists frequently point to the extraordinary high prices of patented ARVs, but the potential for greatly reduced generic prices may in fact be low. FTA critics most often cite two patented drugs, efavirenz by Merck, Inc., and Kaletra by Abbott Laboratories, as essential ARVs with prices far beyond the means of the average HIV/AIDS patient, and call for compulsory licenses for local production in Thailand. However, Merck representatives said that they sold efavirenz in Thailand at a no-profit price in recognition of Thailand,s AIDS situation and developing nation status (though MoPH complains it is chronically in short supply). As well, a survey on ARV pricing by Medecins Sans Frontieres showed that the 600 mg tablet of efavirenz was already being sold in Thailand at the same price as the cheapest generic version in India. It is unlikely that GPO could beat Indian manufacturers on price.

¶24. (SBU) Kaletra, the second-line ARV which is the other frequent target, is sold for $300 a month, ten times the price of generic first-line ARV GPO-vir, but a generic copy would also likely be expensive, at least in the short run. Brazilian generic manufacturers recently claimed that if the patent were broken in Brazil they could manufacture Kaletra for approximately USD 1000 per year, still several times more expensive than GPO-vir.

¶25. (U) At present the likelihood for the RTG to issue a compulsory license on an ARV is low. There are relatively fewer HIV patients who require second-line ARVs in Thailand, and in the short run economies of scale are perhaps too small to warrant local production. However, the MoPH's program to provide ARVs to significantly larger number of HIV positive patients promises to slow the fatality rate from AIDS and increase the overall number of HIV positive patients. As more of these patients move to expensive second-line ARV regimens the additional costs may fuel renewed calls for compulsory licenses for these ARVs.

Can they make the generics?

¶26. (U) The Government Pharmaceutical Organization takes the lead on development of generic copies of innovative drugs, though they also perform their own original research and in fact hold a number of patents. GPO manufactures approximately 300 pharmaceutical products, including a number of generic ARVs. GPO's facilities are generally highly regarded and in a meeting with Econoff, R&D Director Ms. Pisamorn Klinsuwan insisted that GPO had the capability to produce some of the most complicated drugs on the market, including second-line ARVs such as Kaletra were they given the opportunity.

¶27. (SBU) GPO had their eye on producing other patented drugs including blockbuster anti-cholesterol medicine Lipitor, the top-selling drug in Thailand. Pisamorn claimed GPO could produce the drug at half the cost of its current retail price, but admitted that estimate did not include R&D costs. R&D was tallied in a separate budget and not factored

into overall production costs.

¶28. (SBU) Although GPO produces generic copies at substantially reduced prices from original versions, the state-owned firm still faces many of the same market constraints as a private firm. GPO's R&D director told Econoff that GPO was researching all available ARVs for future production, but decisions to produce other drugs were dependent on local conditions. GPO took into account the need for a new drug when deciding whether to produce a generic copy, but like other pharmaceutical companies had to examine the size of the market and whether it would be worth the investment to produce a generic copy. Absence of a patent on an original drug was insufficient criteria to produce a generic. Although GPO is state-owned, it receives no budget support from the RTG and is expected to turn a profit both to expand operations and to provide budgetary support to the RTG.

¶29. (SBU) GPO is preparing to produce the anti-viral medicine Tamiflu, considered to be effective in battling various strains of avian influenza. The original manufacturer, Roche Holding AG, confirmed to the RTG that Tamiflu was not patented in Thailand and that GPO was not restricted from producing the drug nor obligated to pay a licensing fee. GPO is acquiring precursor ingredients from Indian pharmaceutical companies and has claimed it can produce enough Tamiflu for 5000 patients within a year.

Tariff issue

¶30. (U) Pharmaceutical reps in Thailand often take issue with RTG complaints about the need for lower drug prices, noting that Thailand maintains a ten percent tariff on pharmaceutical products, with exceptions for medicines for HIV/AIDS, malaria, thallassaemia and vaccines, which are zero-rated. Zero-rated medicines make up less than ten percent of the value of Thai pharmaceutical imports. A successful conclusion to the FTA and a reduction in tariffs could produce a drop in overall pharmaceutical costs.

Taking the long view

¶31. (U) Although little immediate effect on pharmaceutical costs would appear to be likely after implementation of an FTA with the U.S., Thais are concerned about future drugs entering the pipeline. The HIV/AIDS crisis is diminishing thanks to greatly improved treatment and access to ARVs, but restricted access to future generations of ARVs could set back the progress made to date. Thais are concerned as well that a future vaccine or treatment for avian flu might be marketed at prices beyond their means to prevent an epidemic.

¶32. (U) Analysts do not foresee future difficulties with unreasonable delays in patent and marketing approval processes and resulting lengthening of a drug,s patent term. The importance of ARVs and other life-saving medicines virtually ensures that the RTG would quickly approve patents and marketing for any future treatments or cures. In addition, important drugs of this nature would almost certainly be patented (if a decision were not made to license them locally), and put on the market relatively quickly, and therefore data exclusivity would be unlikely to come into play. Industry observers agree that despite less than rapid service for the typical patent at the Thai Patent Office, additional resources should ensure that few new patent applications face any unreasonable delays.

¶33. (U) Despite predictions of skyrocketing drug prices by anti-FTA activists, the long-term outlook in the pharmaceutical industry has not changed. Company reps in Bangkok did not appear to be altering business models in Thailand in anticipation of a U.S.-Thai FTA and did not expect any significant increases in revenue after its passage. Several company reps were unaware an FTA might have provisions that would affect their products. One analyst explained that the industry was supporting the FTA's patent provisions primarily to help set a precedent for future FTAs in more important markets.

¶34. (U) Comment: The debate over access to medicines and FTAs presents a dichotomy of goals: access to cheap and effective medicines for patients who need them now, but incentives for development of innovative drugs for the future as well. The hard truth is that without economic incentives to manufacture an innovative new drug, it won,t be made; if no market exists in Thailand for a new drug to be sold profitably, it won,t be marketed, even by Thai generic manufacturers.

¶35. (U) Inevitably, some drugs would be affected by an FTA and raise overall pharmaceutical costs, though the increased costs of individual drugs could be offset by tariff reductions on pharmaceutical imports overall. Thailand has an advantage in that it has a sizable market for new

medicines and can promote competition, and has also developed a strong generic industry to compete with off-patent drugs. Its generic industry's ability to copy most any drug also backs up the occasional threat to issue a compulsory license and helps persuade companies to keep prices lower than they might otherwise. However, Thailand's program to provide HIV medicines to more patients portends a future of skyrocketing health care costs as HIV-positive patients live longer and move on to expensive second-line regimens. The threat of a compulsory license may one day cease to be only a threat. End comment.

¶36. (U) Embassy expects an uphill battle against organized opposition to the FTA and overcoming fears among Thais of skyrocketing drug prices and a widening HIV/AIDS crisis. As part of an overall outreach effort, Embassy suggests use of the following talking points regarding pharmaceutical costs and the FTA:

-- No provision exists in the IPR chapter of the U.S.-Thai FTA that would encourage pharmaceutical companies to raise prices for their products. On the contrary, a reduction in the ten percent tariff on most pharmaceutical imports could reduce prices for many drugs in Thailand.

-- Few essential drugs would likely be granted additional market exclusivity by an FTA. We know of no anti-retroviral medicines to treat HIV patients that would be affected.

-- Additional resources from the RTG to improve patent and marketing approval procedures would go far to removing the potential for patent term extensions on individual drugs, and speed essential drugs to patients as well.
BOYCE